

**REMARKS**

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

**I. Status of the claims**

The Office Action lists claims 1-10 as rejected, and claims 10-12 as withdrawn. To clarify the status of claim 10, Applicants' representative called the Examiner on March 27, 2009, who courteously clarified that claim 10 is withdrawn and not rejected *i.e.*, claims 10-12 are withdrawn, and claims 1-9 are rejected. The presently filed communication proceeds on that basis of understanding.

Claims 1, 9 and 10 are amended and claims 13-15 are new. The amendments to claim 1 are supported by the specification at page 9, lines 12-26, page 10, lines 14 to 26, original claims 6 to 8, and Figure 6. The amendments to claim 9 are supported by the specification at page 3, lines 24-28 and Example 8, which demonstrates that the proportion of fucose-free sugar chains is 30% or more. With the incorporation of claims 6-8 into claim 1, claim 10 is amended from dependence from claim 7 to dependence from claim 1. New claims 13-15 each recite individual species within claim 1, and are supported by claim 1 and compounds I, J and K in Figure 6 of the specification. None of these amendments introduce new matter.

After the foregoing amendments, 6-8 are cancelled, and claims 10-12 are withdrawn as corresponding to the non-elected species. Applicants respectfully request rejoinder and examination of method claims 10-12 following allowance of the product claims. Because claims 10-12 depend from the product claims they do not require further amendment to read on the allowable product. MPEP § 821.04

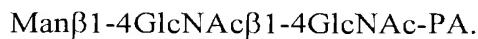
The foregoing amendments, new claims and cancellations are made to advance prosecution and without prejudice or disclaimer of any subject matter removed by amendment or cancellation, reserving all rights to pursue such subject matter in continuing applications.

## II. Rejection under 35 U.S.C. § 102.

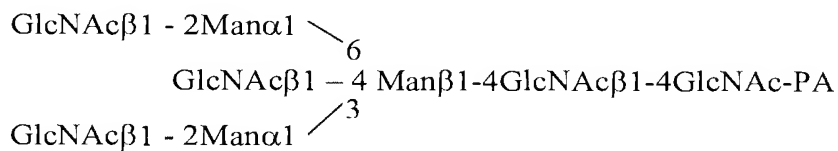
At page 2 of the Office Action, claims 1-9 are rejected as allegedly anticipated by Patent Application Publication No. US 2003/0115614 A1, to Kanda *et al.* (“Kanda”). Applicants respectfully traverse the rejection as it might have been applied to pending claims 1-4 and 9.

### A. Claims 1-4 and 9

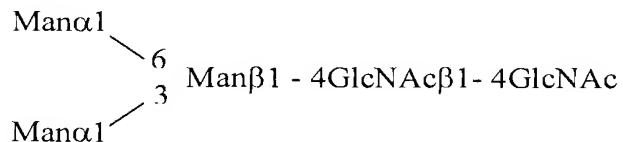
Claim 1 is drawn to a sugar chain-altered antibody (anti-HM1.24 antibody) against HM1.24 antigen, wherein the antibody comprises a sugar chain which includes N-glycoside-linked sugar which has a basic structure



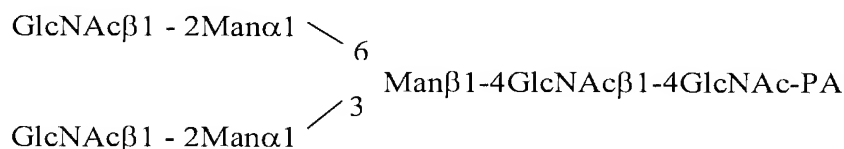
wherein said sugar chain does not contain  $\alpha$ -1,6 core but contains a bisecting N-acetylglucosamine (GlcNAc) which is bound with a  $\beta$ -1,4-linkage on the mannose (Man) of the basic structure. This sugar chain reads on, for example, species I-J as shown in Figure 6 of the specification. Species I is exemplary:



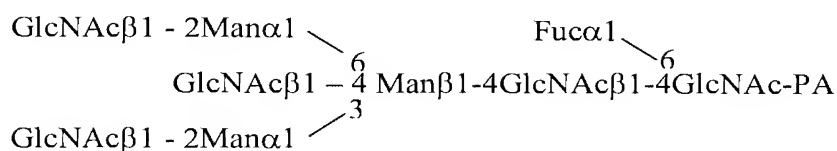
Kanda does not read on claim 1. In Kanda, the bisecting N-acetylglucosamine is attached to the nonreducing end side of the core structure (see, paragraph [0259] of Kanda). Thus, according to paragraph [0008], the core structure is represented by the following structure:



The non-reducing end of the core structure in Kanda is formed by two mannose units shown on the left-most side of the above structure. In Example 11 two bisecting N-acetylglucosamine (GlcNAc) units are bonded to the above-mentioned two mannose units so as to form the following structure, as seen at paragraph [0885] of Kanda:



In analysis of the sugar groups on glycosylated antibodies, Kanda also describes the following structure at paragraph [0885]:



Here, the bisecting N-acetylglucosamine is attached to the Mannose before branching, but also has an  $\alpha$ -1,6 core fucose. This sugar chain therefore also differs from that described in claim 1, which explicitly *excludes* a fucose side chain.

Claim 1 is not anticipated by Kanda, therefore. It follows that claims 2-4 and 9, which depend from claim 1, similarly are not anticipated. Reconsideration and withdrawal of the rejection is respectfully sought.

### B. Claim 9

Claim 9 is further distinct from Kanda, because it recites “wherein of all sugar chains on said antibody the relative ratio of all fucose-free sugar chains is 30% or more.” Kanda does not provide this element.

The Office Action at page 2 cites to paragraph [0264] of Kanda and asserts that it provides “30% or more fucose-free antibodies.” Applicants respectfully disagree because anticipation requires not only that the reference disclose each and every element of the

claimed invention, (*Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369, 1375 (Fed. Cir. 2006)), it must *also* “enable one of ordinary skill in the art to make the invention without undue experimentation.” *Impax Labs, Inc. v. Aventis Pharms. Inc.*, 545 F.3d 1312, 1314 (Fed. Cir. 2008); *see also In re LeGrice*, 301 F.2d 929, 940–44 (CCPA 1962).

Kanda does not enable total fucose-free sugar chain above 30%. Indeed, in the Examples, Kanda manages at most 20% of fucose-free sugar chains, as shown by the experimental results in paragraph [0083]. Kanda appears to acknowledge that only the 20% limit is enabled, as all additional descriptions in Kanda, including the claims, is limited to 20%. Because Kanda cannot enable beyond 20%, Kanda cannot anticipate the “above 30%” element of claim 9. For at least this additional reason, Kanda does not anticipate claim 9. Reconsideration and withdrawal of the rejection is respectfully sought.

### **III. Rejoinder and allowance of claims 10-12**

All of the method claims (*i.e.*, claims 10-12), depend from and therefore incorporate the limitations of claim 1, a product claim. Because all product claims are believed to be allowable, rejoinder, examination and allowance of the method claims is proper at this time.

**CONCLUSION**

Applicants believe that all claims are allowable.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Any incorrect or missing payment should also be charged to the deposit account. If any extensions of time are needed, Applicants hereby petition under 37 C.F.R. §1.136 for such extension and authorizes payment from the deposit account.

Respectfully submitted,

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